Developing Medical Devices for Pediatric Patients: Engineering Considerations

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FDA Public Workshop

January 8, 2014

Overview

- Pediatric Population
- Device and Design Considerations
- Unique and Unmet Needs
- Creative Approaches

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Pediatric Population

- Pediatric
  - Patients ≤ 21 years at the time of the diagnosis or treatment
- Pediatric "subpopulation"
  - Neonates (birth – 1 month)
  - Infants (>1 month – 2 yrs)
  - Children (>2 yrs – 12 yrs)
  - Adolescents (>12yrs – 21 yrs)
- Defined in *Premarket Assessment of Pediatric Medical Devices Guidance*, available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089740.htm

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Device & Design Considerations

- Pediatric population represents a particularly vulnerable group
- General principles of device review also apply to pediatric devices
  - Biocompatibility, sterility, EMC
  - Design controls and good manufacturing practices (GMP)

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Device & Design Considerations

- Additional considerations for pediatric populations
  - Height and weight
  - Unpredictable growth and development issues (and growth in general)
  - Disease or condition
  - Congenital problems
  - Hormonal influences
  - Anatomical and physiological differences from the adult population
  - Activity and maturity level
  - Injury and recovery
  - Difficulty conducting clinical trials

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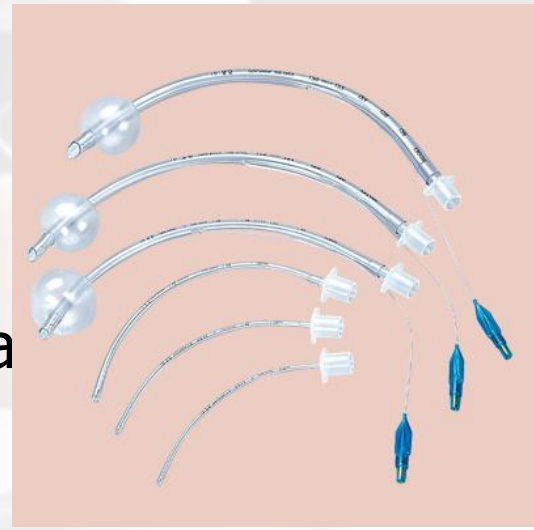
Device Design



- Modifications to an adult device
  - Reduction in size
  - Attenuation of electrical output
- Designed specifically for pediatric popula
  - To address a pediatric specific condition
  - To address pediatric limitations
- Need to consider factors specific to pediatric population
  - Additional stresses on the device due to growth
  - Activity level of pediatric patients
  - Impact of treatment on smaller patient
  - Affects of treatment on development

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Pediatric AED Pads

- AED Manufacturers recognize the need for lower output for children
- Different design options
  - Pediatric pads that attenuate signal
  - User input to AED to signal that patient is a child

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VEPTR

- Vertical Expandable Prosthetic Titanium Rib (VEPTR) (Synthes) is indicated for treatment of Thoracic Insufficiency Syndrome (TIS) in skeletally immature patients.
- Curved metal rod attached to ribs
- Device is lengthened or replaced at specific times to allow for patient's growth and to further correct deformity

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Berlin Heart

- Berlin Heart EXCOR Pediatric Ventricular Assist Device (VAD) is a blood pump that vibrates rhythmically and is designed to assist patients who cannot pump enough blood with their own natural heart.
- First FDA-approved pulsatile mechanical circulatory support device specifically designed for children.
- Adult heart assist devices were too large to be used in children

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Collaboration

FDA wants to work with manufacturers and the clinical community to bring to the market more devices designed for and evaluated in children – with appropriate labeling.

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Contact Information

Thank you!

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